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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,099	01/16/2001	Rebecca E. Cahoon	BB 1159	3054

7590

12/19/2003

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,099

Applicant(s)

CAHOON ET AL.

Examiner

Christian L Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-42 and 46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 34-42 and 46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 12/2/2003 has been entered.
2. Claims 34-42 and 46 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
4. Claims 34-42 and 46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.
Applicants disclose the nucleotide sequences of SEQ ID NO: 5, the deduced amino acid sequence of the protein encoded as SEQ ID NO: 6, and assigned the protein of SEQ ID NO: 6 as a 3-dehydroquinate synthase based on percent identity to a reference protein in the prior art. However, the specification does not disclose the **specific** function of the protein of SEQ ID NO: 6 or any activity assays to demonstrate that the protein has 3-dehydroquinate synthase activity. Homology is not a disclosure of how to use the protein or polynucleotide encoding the protein of SEQ ID NO: 6. The specification does not explicitly state that homology to a reference polypeptide known in the prior art is a disclosure that the claimed polypeptide has the properties and biological function of the reference polypeptide relied upon.
Substantial utility is one that provides a specific benefit in currently available form at the time of filing of the invention. However, the main utility of the nucleic acid and protein is to carry out further research to identify the biological function associated with the protein. Utilities that require or constitute carrying out further research to identify or reasonably confirm a specific use are not substantial utility and do not provide a specific benefit. Thus, the claimed invention has no specific or substantial asserted utility.

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Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 34-42 and 46 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 34-42 and 46 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, claims 34-42 and 46 which encompass any isolated polynucleotide encoding a polypeptide having 3-dehydroquinate synthase activity, wherein the amino acid sequence of the polypeptide and the amino acid sequence of SEQ ID NO: 6 have at least 80%, 90%, or 95% identity based on the Clustal alignment method are not enabled by the specification.

Applicants' arguments filed 12/2/2003 have been fully considered but they are not persuasive. Applicants' position in addition to the reasons of record is that Carpenter et al. has a publication date of July 16, 1998 which is prior to the priority filing date of the instant application.

The Examiner agrees with applicants that the Carpenter et al. reference has a publication date prior to the priority filing date of the instant application but maintains for reasons of record as supplemented in the instant Office Action that the amount experimentation to make the claimed invention is undue.

Only nine catalytic residues are identified as being conserved while the entire protein is composed of 437 amino acids. The specification as originally filed does not explicitly account for and identify the other amino acid residues that can or cannot be changed without any loss of enzyme activity to make the claimed invention. Furthermore, the specification provides guidance for screening and searching for the claimed invention which is **not guidance for making the claimed invention**.

Thus, searching for the specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in any polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 6 in order to make a polypeptide that has an amino acid sequence has at least 80%, 90%, or 95% identity to SEQ ID NO: 6 is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polynucleotide encodes a protein that has 3-dehydroquinate synthase activity is extremely low since no information is provided by the specification regarding the specific amino

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acid residues that can or cannot be changed without any loss of enzyme activity. Claims 39-42 and 46 which depend from defective claim 34 are also rejected because they do not correct the defect of claim 34.


Amending the claims to recite that the isolated polynucleotide encodes a dehydroquinase synthase comprising the amino acid sequence of SEQ ID NO: 6 may overcome the rejection.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF


PONNATHAPURA ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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